

REMARKS

I. Status Summary

Claims 1, 3-5, 8, 11 and 12 are pending in the present application and have been examined by the U.S. Patent and Trademark Office (hereinafter the "Patent Office"). Claim 12 has been allowed and claims 1, 3-6, 8 and 11 presently stand rejected. Claims 2, 6, 7, 9, and 10 have been canceled. New claim 13 is added by the present amendment. Therefore, upon entry of this Amendment, claims 1, 3-5, 8, and 11-13 will be pending.

II. Allowed Claims

In the Conclusion, on page 6 of the Official Action, the Patent Office states that claim 1 is allowed but applicants believe this is a typographical error. Applicants believe that the Patent Office intended to state that claim 12 is allowed as is stated in the Office Action Summary on page 1 of the Official Action.

Applicants thank the Examiner for the allowance of claim 12 as indicated above. Reconsideration of the application as amended and based on the remarks set forth hereinbelow is respectfully requested.

III. Claim Rejections - 35 U.S.C. § 112, First Paragraph, New Matter

Claims 1, 3-5, 8 and 11 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. The Patent Office contends that the phrase, "steroid hormone-producing enzymes" in claim 1 is new matter. The Patent Office contends that applicants might not have contemplated cells

that produce steroid hormone-producing enzymes. After careful consideration of the rejection and the Patent Office's basis therefor, applicants respectfully traverse the rejection and submit the following remarks.

Applicants respectfully submit that "cells that produce an enzyme that produces steroid hormone" are "steroid hormone producing cells." If a cell expresses a "steroid hormone-producing enzyme" the cell produces steroid hormones. Thus applicants respectfully submit that there is no new matter in the amendment from "steroid hormone-producing cells" to "cells that produce steroid hormone producing enzymes." Further, the language of claim 1 is supported by the specification, as described below.

Furthermore, applicants respectfully submit that:

[i]f the body of a claim fully and intrinsically sets forth all the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999).

MPEP 2111.02.

The body of claim 1 recites the specific steroid hormone producing enzymes produced in the examples of the specification, line by line support for which was provided in the response filed March 29, 2010 and is repeated hereinbelow. Applicants respectfully submit that the body of claim 1 fully sets forth the limitations of the presently claimed subject matter.

Support for the mesenchymal stem cells (MSC) producing the list of steroid hormone-producing enzymes of claim 1 (p450scc, p450c17, HSD3b1, StAR, 3 β -HSD, p450 c21, p450 11b1, and HSD3b6) can be found in the specification in Example 1,

page 7, line 5 (for cells producing enzyme p450scc); Example 2, page 7, lines 13-14 (for cells producing enzymes p450scc, p450c17, and HSD3b1); Example 3, page 8, lines 14-15 (for cells producing enzymes p450scc, StAR, 3 β -HSD, p450 c21, and p450 11b1); and Example 5, page 9, lines 17-27 (for cells producing enzymes p450scc, HSD3b1, and HSD3b6).

Additional support for the phrase “cells that produce steroid hormone-producing enzymes” can be found in the specification on page 2, lines 4-6 (discussing that steroid hormone producing enzymes are induced in human cells in Example 3); page 7, lines 8-16 (discussing that the expression of the enzymes p450scc, HSD3b1, and p450c17) was induced in cells); and on page 6, Table 1 (describing the enzymes recited in claim 1 as steroid hormone producing enzymes).

In regard to this new matter rejection, claims 3-5, 8 and 11 are believed to only be rejected for depending from claim 1. Accordingly, for at least the reasons provided hereinabove, it is respectfully submitted that claims 1, 3-5, 8 and 11 are free of new matter and this rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn. It is respectfully submitted that claims 1, 3-5, 8 and 11 are now in proper condition for allowance and a notice to that effect is respectfully solicited.

IV. Claim Rejections - 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1, 3-5, 8 and 11 are rejected under 35 U.S.C. §112, first paragraph, for an alleged lack of enablement. The Patent Office acknowledges that there is support for differentiating MSC, by transfecting the cells with a vector encoding SF-1, into cells that produce progesterone, androgen, and androstendione. See Official Action, page 3,

lines 13-16. But, the Patent Office contends that there is insufficient support for differentiating MSC into cells that produce the steroid hormone-producing enzymes recited in claim 1 “*without producing hormones*” (emphasis added). *Id.*, lines 18-19. Regarding claim 1, the Patent Office also contends that it would have required undue experimentation to determine how to use the method claimed to differentiate MSC into cells that produce the recited enzymes without producing hormones such as progestin, androgen, and androstendione. *Id.*, page 6, lines 3-6.

After careful consideration of the rejection and the Patent Office’s basis therefor, applicants respectfully traverse the rejection and submit the following remarks.

Applicants direct the Patent Office’s attention to the language of claim 1. A careful reading of the claim shows that there is no requirement recited in the claim that hormones are not produced. As such, applicants respectfully submit that based contentions of the Patent Office, the amendments to claim 1 filed in the response dated March 29, 2010 might have been misread.

The Patent Office also contends that claim 1 encompasses differentiating MSC into **any** cells that produce the recited steroid hormone-producing enzymes. *Id.*, page 5, lines 7-8. This allegedly includes cells that do not produce hormones.

Applicants respectfully disagree. As discussed above in relation to the “New Matter” rejection, if a cell expresses a “steroid hormone-producing enzyme,” the cell produces steroid hormones. Thus the claims do not encompass cells that produce steroid hormone-producing enzymes without producing hormones.

Continuing, the Patent Office contends that: (1) Example 1 of the specification “fail [sic] to show the cells produce pregnenolone or any other hormone claimed (Official

Action, page 4, last paragraph); (2) Example 2 of the specification “fail [sic] to show the cells produce progesterin, estrogen, glucocorticoid or mineralcorticoid as claimed” (Official Action, page 5, lines 3-5); and (3) Example 3 of the specification “fails to shows [sic] the cells produce any hormones as claimed” (Official Action, page 5, line 8).

Applicants respectfully submit that the claims are drawn to differentiating MSC into cells that produce the steroid hormone-producing enzymes as recited in claim 1. The present specification is believed to fully support present claim 1. In this regard the Patent Office's attention is directed to the portions of the specification cited herein above. As such, this contention is believed to be addressed.

Claim 11 recites a method of producing the hormones progesterone, androstenedione, and androgen. As discussed above, the Patent Office has acknowledged that a method of differentiating MSC into cells that produce these hormones is enabled. See Official Action, page 3, lines 13-16. See also Example 2, page 7, lines 25-28, of the specification as filed for additional support for claim 11.

Accordingly, for the reasons discussed hereinabove, it is respectfully submitted that the rejection of claims 1 and its dependent claims under 35 U.S.C. § 112, first paragraph should be withdrawn. Applicants further submit that claims 1, 3-5, 8, and 11 are in proper condition for allowance and respectfully solicit a Notice of Allowance to that effect.

V. New Claim

New claim 13 has been added by this amendment as indicated above. Claim 13 is essentially previously presented claim 1 rewritten without the reference to steroid

hormone-producing enzymes in the preamble. No new matter has been added. Support for this amendment can be found in the specification in Example 1, page 7, line 5 (for enzyme p450scc); Example 2, page 7, lines 13-14 (for enzymes p450scc, p450c17, and HSD3b1); Example 3, page 8, lines 14-15 (for enzymes p450scc, StAR, 3 β -HSD, p450 c21, and p450 11b1); and Example 5, page 9, lines 17-27 (for enzymes p450scc, HSD3b1, and HSD3b6).

Therefore, applicants submit that new claim 13 is allowable over the prior art and respectfully solicit a Notice of Allowance to that effect.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

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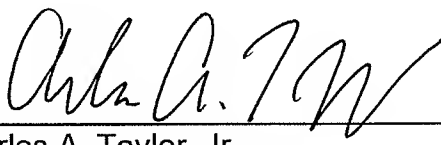
DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any deficiencies of payment, or credit any overpayment associated with the filing of this Amendment to Deposit Account No. 50-0426.

Respectfully submitted,

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Date: 07/12/2010

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